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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,126	11/28/2000	Hui-Quan Han	01017/35966A	5693

4743 7590 11/27/2002

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 11/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,126

Applicant(s)

HAN ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 9,12-45,49-58,65 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8,10,11,46-48 and 59-64 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 18 September 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed September 18, 2002 amending the specification to correct typographical errors and amending claims 1-3 and 59-62 has been entered.

Claims 1-66 are pending. Claims 9, 12-45, 49-58, 65 and 66 are withdrawn.

Claims 1-8, 10, 11, 46-48 and 59-64 are under consideration.

Drawings

The drawings filed concurrently with the application on November 28, 2000 have been objected by Draftsman, please refer to the attached form PTO-948 for details.

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on September 18, 2002 have been approved by the examiner. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Specification

The amendment filed September 18, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: various

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previously not recited positions such as 4657 in SEQ ID NO:18, for example.

Applicants are required to provide detailed explanation why these new positions do not introduce new matter into the disclosure or to cancel the new matter in the reply to this Office Action.

Claim Objections

Claims 1-3 are objected to because of the following: in claims 1 and 2, "and" is missing between clauses (b) and (c). In claim 3, "and" is missing between clauses (c) and (d).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-8, 10, 11, 46-48 and 59-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 2(b) and 59 are drawn to a DNA encoding an allelic or splice variants of SEQ ID NO: 1 encoding a polypeptide with human E3 α ligase activity. Therefore, the claim encompasses a diverse genera of molecules of different and unknown structures described by function. The specification discloses only one allelic or splice variant within the scope of the genus: SEQ ID NO:1. It discloses one SNP (pages 96-97, Example 9; SEQ ID NO:18). There is no description of other mutational sites for allelic variants or exon/intron splice junction for splice variants that exists in nature, and there is no description of how the structure of SEQ ID NO: 1 or SEQ ID NO:18 relates to the structure of other allelic or any splice variant. Allelic or splice variants are variant structures, and in the present state of the art the structure of one or two does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill on the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of the genus is not representative of the variants of the genus and is insufficient to support the claim.

Claim 3 is drawn to a DNA that encodes a polypeptide having at least one substitution, insertion or deletion, or a C and/or N-terminal truncation in SEQ ID NO:2 and retaining human E3 α ligase activity of SEQ ID NO:2. The claim does not place any limit on the number of amino acid substitutions, insertions and deletions that may be made to SEQ ID NO:2. This amounts to the claim directed to a genus of DNA molecules encoding any polypeptide with human E3 α ligase activity. Thus, the scope

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of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members is permitted. The specification discloses only a single species, SEQ ID NO:1, of the claimed genus. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of encoding a polypeptide with human E3 α ligase activity and fails to provide any structure: function correlation present in all members of the claimed genus.

Claims 4-8, 10, 11, 46-48 and 60-64 are drawn to vectors, host cells and methods of use of the above DNAs and are included in the rejection as dependent from the product lacking sufficient written description.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 3-8, 10 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleotide encoding SEQ ID NO:2 and a fragment thereof retaining human E3 α ligase activity, does not reasonably provide enablement for a nucleotide encoding a polypeptide having human E3 α ligase

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activity comprising a fragment or variant of SEQ ID NO: 2 of unknown structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any sequence that comprises a fragment of SEQ ID NO:2 and encodes a polypeptide retaining human E3 α ligase activity because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the specific requisite activity of the polypeptide of the instant invention; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D)

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the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide structure having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-8, 10, 11, 46-48 and 59-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "human E3 α ligase activity". The specification does not specifically define "human E3 α ligase activity". The specification does not state how this activity is different from an ubiquitin ligase activity, for example, rendering the metes and bound of the claims unclear.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-8, 10, 11, 46-48 and 59-64 are rejected under 35 U.S.C. 102(a) as

being anticipated by Hillier et al.

Hillier et al. teach a human EST of 682 bp that is 99.3% identical to SEQ ID NO:1 and encodes an ubiquitin protein ligase E3 component (EST Accession AI929033). Said EST comprises a fragment, a variant, an allele of SEQ ID NO:1.

Claims 2-8, 10, 11, 46-48 and 59-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Strausberg et al.

Strausberg et al. teach a human EST of 641 bp that is 99.5% identical to SEQ ID NO:1 and encodes an ubiquitin protein ligase E3 component (EST Accession AI361043). Said EST comprises a fragment, a variant, an allele of SEQ ID NO:1.

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Claims 3-8, 10, 11 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Varshavsky et al.

Varshavsky et al. (US Patent 5,861,312) teach a murine UBR1 (SEQ ID NO:1) that is 70.3 % identical to SEQ ID NO:1 of the instant invention. They teach that UBR1 is one of several E3-type proteins (column 4, lines 1-2). Because the specification does not teach how human E3 α ligase activity is different from an E3-type protein activity, supra, the DNA taught by Varshavsky et al. encodes a fragment or a variant of SEQ ID NO:1.

Response to Arguments

Applicant's arguments filed September 18, 2002 have been fully considered but they are not persuasive.

With regard to the written description rejection, Applicants argue that they "have disclosed two species of the claimed genus and members of the claimed genus can be identified by common attributes, which are described in the amended claims as those demonstrating "human E3 α ligase activity", thus providing a structure:function attribution" (page 15 , 1st paragraph). This is not persuasive because "a structure:function attribution" is provided only for two disclosed species which Applicants are entitled to. However, the disclosure of only two species within a variable

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genus is insufficient to represent the entire genus because said "a structure:function attribution" common to all members of the genus is not described.

With regard to the enablement rejection, Applicants argue that they "have amended claims 1-3 and 59 by defining the claimed sequences with a combination of structural and functional limitations that are enabled by the specification (page 15, 3rd paragraph). This is not persuasive because with regard to claim 3, which is rejected, there is no structural limitations because "comprising at least one" modification does not limit the number of modifications negating, in effect, any reference to the sequence identifier.

With regard to the 102 rejections over Hillier et al. and Strausberg references, Applicants argue that they "fail to encode a protein having the activity recited in, e.g., claims 2, 3 and 59". This is not persuasive because said activity is recited in the annotations to said ESTs.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner

November 22, 2002